K071081.St

031

510(k) Summary

DexcoWinA ADX4000
Cordless Portable Dental X-ray System

Common/Classification Name:

JUL - 5 2007

Unit, X-Ray, Extraoral With Timer

21 CFR 872.1800

Sponsor:

Dexco
Attn: Henry Jang, Vice-President
1102, 3rd E&C Venture Dream Tower
197-33 Guo-dong, Guro-gu
Seoul
(South) Korea

Contact:

RegTech Solutions, LLC;
Attn: Robert Mazzaferro, Manager
11 Dellcastle Court;
Montgomery Village, MD 20886

Prepared: March 20, 2007

LEGALLY MARKETED PREDICATE DEVICE

For its indication for use, the DexcoWinA ADX4000 Cordless Portable Dental X-ray System is substantially equivalent to the Nomad Dental X-ray System cleared by FDA under K051795.

DEVICE DESCRIPTION

The DexcoWinA ADX4000 Cordless Portable Dental X-ray System is a battery-powered hand-held dental x-ray machine whose fixed output is 60 kV_p (Constant Potential). It can be used with either a digital sensor or conventional film. This is a prescription device that can be used on pediatric and adult patients.

SUBSTANTIAL EQUIVALENCE SUMMARY

A comparison of the DexcoWinA ADX4000 Cordless Portable Dental X-ray System and the Nomad™ Dental X-ray System is presented in Table 1.

Table 1 Comparison with predicate device

Feature	DexcoWinA ADX4000 (New Device)	NOMAD™ (Predicate Device K051795)
INTENDED USE:	The ADX4000 Cordless Portable Dental X-ray System is indicated for use only by trained and qualified dentists or dental technician for both adult and pediatric subjects for taking diagnostic extraoral dental X-rays using intraoral digital or film sensors.	The NOMAD Dental X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subject as an extraoral diagnostic dental x-ray sources to produce X-ray images using intraoral image receptors.
MECHNICAL:		
Size: Body	5.5"H x 6.5"W x 3.2"D	13"L x 11.5"H x 5.5"W
Weight	4.4lbs.	8.5lbs
Source to skin distance	20cm	20cm
Cone diameter	5cm	6cm
User Interface	Up-down and left-right buttons for exposure time selections with display	Up-down buttons for exposure time selections, with timer display
Backscatter radiation protection	Circular scatter shield	6.75"dia. Pb-filled acrylic plastic scatter shield
Exposure switch	On tubehead assembly, or at control panel	On tubehead assembly/ control panel
Tubehead mounting	Handheld, or on a tripod	Handheld
ELECTRICAL:		
Energy Source	Rechargeable 16.8V DC Li-Polymer battery pack	Rechargeable 14.4V DC NiCd battery pack
Exposure Time	0.01-1.35 seconds in 0.01 increments	0.01-0.99 seconds in 0.01 increments
Timer Accuracy	±(10% + 1ms)	±(10%+1ms)
mA	1mA fixed	2.3mA fixed
kVp	60kVp fixed	60kVp fixed
Waveform	Constant Potential (DC)	Constant Potential (DC)
Duty Cycle	1:60	1:60
Electrical Safety Standards	IEC60601-1 & others	IEC60601-1 & others.
Electromagnetic Standards	EN60601-1-2 & others	IEC60601-1-2
X-RAY PERFORMANCE	21 CFR 1020.30, 1020.31 IEC60601-1-3	21 CFR 1020.30, 1020.31 IEC60601-1-3 IEC60601-2-7

CONCLUSION

As can be seen in the comparison table above the DexcoWinA ADX4000 & its suggested predicate, the Nomad, have the same intended use and are nearly technically the same. We therefore believe that the ADX4000 is substantially equivalent to the Nomad.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL - 5 2007

DexcoWinA
% Mr. Robert Mazzaferro
Manager
RegTech Solutions, LLC
11 Dellcastle Court
MONTGOMERY VILLAGE MD 20886

Re: K070811
Trade/Device Name: ADX4000 Cordless Portable Dental X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: June 18, 2007
Received: June 18, 2007

Dear Mr. Mazzafferro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070811

Device Name: ADX4000 Cordless Portable Dental X-ray System

Indications for Use: The ADX4000 Cordless Portable Dental X-ray System is indicated for use only by trained and qualified dentists or dental technician for both adult and pediatric subjects for taking diagnostic extraoral dental X-rays using intraoral digital sensors or film.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K070811